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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/517,558	07/13/2005	Richard Frank Tester	08830-0307US1	2680

23973 7590 08/18/2010

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EXAMINER	
PALENIK, JEFFREY T	

ART UNIT	PAPER NUMBER
1615	

NOTIFICATION DATE	DELIVERY MODE
08/18/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/517,558	TESTER ET AL.	
	Examiner	Art Unit	
	Jeffrey T. Palenik	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 June 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,5,7-12 and 25-29* is/are pending in the application.

4a) Of the above claim(s) *26-29* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,5,7-12 and 25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

STATUS OF THE APPLICATION

Applicants' amendments and remarks, filed 21 June 2010 regarding Application N° 10/517,558, are acknowledged and entered on the record. The Examiner acknowledges the following:

Claims 4, 6, 36 and 37 are newly cancelled.

Claims 1 and 5 have been amended. Claim 1 adds a limitation to the formulation wherein said formulation is a "buccal melt product" which comprises the previously claimed freeze-dried matrix product. Support for the amendment is found in cancelled claim 4.

Claim 5 appears to be amended to properly depend from the base claim instead of cancelled claim 4. Though the amendment is proper in its dependency and subject matter and raises no new matter issues, Applicants are cautioned against the submission of non-compliant claim amendments. Claim 5 should reflect the proper indicator: "(Currently Amended)", per MPEP §714.

No new claims have been added.

No new matter has been added.

Thus, claims 1, 3-5, 7-12 and 25 now represent all claims currently under consideration.

INFORMATION DISCLOSURE STATEMENT

No new Information Disclosure Statements (IDS) have been filed for consideration.

SPECIFICATION

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code (see MPEP §608.01).

The website (http://www.foodstarch.com/directory) appears twice in the disclosure (pg. 5, line 11 and on page 35, line 2).

WITHDRAWN OBJECTIONS/REJECTIONS

Claim Objection

Applicants' cancellation of claim 36, as discussed above, renders moot the objection. Thus, said objection stands **withdrawn**.

MAINTAINED REJECTIONS

The following rejection is maintained from the previous Office Correspondence dated 21 January 2010 since the art which was previously cited continues to read on the amended limitations.

CLAIM REJECTIONS - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 3-5, 7 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ameraal et al. (USPN 5,482,560) [*emphasis added to reflect cancelled claims*].

Amended claim 1 is directed to a bioadhesive pharmaceutical formulation comprising an active agent and a mucoadhesive carrier for said agent wherein said carrier is β-limit dextrin (BLD) and wherein said formulation is in the form of a freeze-dried (lyophilized) matrix. Claim 36, as discussed above, is interpreted by the Examiner as reciting the same limitations as claim1. Claim 3 further limits the active agent to a pharmaceutically active agent. The composition is recited as being in the form of a buccal-melt product (claim 4) which is further limited to a wafer (claim 5) and also recited as a thin-film (claim 7). Herein, and for the purposes of examination

on the merits, the Examiner broadly and reasonably interprets a wafer as being a form of or species of a thin film. Claim 25 recites that the β-limit dextrin of claim 1 is obtained by hydrolyzing a waxy starch.

The invention to Ameraal expressly teaches producing BLD by first forming an aqueous slurry of dull waxy (duwx) starch followed by using well-known drying techniques to recover the final product. Freeze-drying is one such technique that is used (col. 2, lines 47-60). Concerning the remaining limitations of claim 1, the invention of Ameraal is also directed to uses of BLD, specifically teaching that BLD's originating from dull waxy starch are more soluble and stable in aqueous solutions than conventional β-limit dextrin compounds thereby making them excellent carriers (Abstract). Ameraal further discloses that the practiced BLDs, while being very soluble, are useable for slow-release of different compounds such as sweeteners and drugs (col. 1, lines 63-67). Regarding the structural limitations for the final product recited in claims 4, 5 and 7, the reference also teaches that BLD, in addition to being useful as a carrier for volatile ingredients (e.g. drugs, evaporative compounds) is also useful in extruded products as well as being useful as a thickener in gum candies (col. 1, lines 47-52).

Though it is not expressly stated that the products comprising the β-limit dextrins produced by Ameraal are made into thin film/wafer-shaped buccal melts, the teachings of Ameraal would have rendered such a concept *prima facie* obvious to a person of ordinary skill at the time the instant invention was conceived. Ameraal teaches and suggests using the aforementioned BLD as a carrier for such orally administered compounds as sweeteners and drugs. It is also suggested that such compositions may be used in oral products which are produced via extrusion, which further suggests to the ordinarily skilled artisan that such products

are at one point malleable and can be made to take on any shape. As such, it is the position of the Examiner that the aforementioned product structure limitations are a design choice within the purview of the artisan to select.

Thus, based on the teachings of the reference, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, alone or in combination, especially in the absence of evidence to the contrary.

RESPONSE TO ARGUMENTS

Applicants' arguments with regard to the rejection of claims 1, 3, 5, 7 and 25 under 35 USC 103(a) as being unpatentable over the teachings of Ameraal et al. have been fully considered but they are not persuasive.

Applicants allege that the amendment to claim 1 wherein the formulation is in the form of a *buccal melt product comprising* the freeze dried matrix is sufficient in overcoming the rejection particularly since the reference is silent to any mention of said buccal-melt product or any of the seven properties attributable thereto, as discussed on pages 5-6 of the Response. Applicants continue to assert, with respect to said properties, that the composition provided by Ameraal does not subscribe to the quick or "flash melt" release property of an active agent in the oral cavity. It is further argued that the reference teaches away from the use of β-limit dextrins in buccal melt products since "a slow release product as described by Ameraal et al. would not have the most important property of all necessary for a buccal-melt, that of rapid release of the active agent."

Lastly, Applicants allege that there is no teaching provided concerning the formation of a buccal-melt product.

First, in response to Applicants' argument that the references fail to show certain features of Applicants' invention, it is noted that the features upon which Applicants rely (i.e., rapid release of an active ingredient) are not recited in the rejected claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Second, regarding the buccal-melt product formulation limitation, the Examiner continues to accord this term the broadest reasonable interpretation based on Applicants' instant disclosure (MPEP §2111). This includes that which is not only gleaned from the instant disclosure, but also from those references which are properly incorporated by reference into said disclosure (e.g. Ohno reference). From the instant disclosure itself, Applicants' discussion of a buccal-melt type formulation can include rapid release oral dose products (see pg. 9, lines 18-28). However, it is noted that Applicants appear to rely on a supplemented definition from the reference to Ohno et al. (USPN 5,958,453) which is drawn expressly to solid pharmaceutical preparations with improved ability to disintegrate/dissolve in the buccal cavity (Title; Abstract). This reference is directed to a chemical formulation and structure which is markedly distinct from that which is instantly claimed. Essentially the reference is directed to a tablet form, whose chemical makeup ensures increased dissolution and disintegration for faster release of the drug wherein placement of the formulation is in the buccal cavity. The buccal cavity is arguably targeted and selected given its well known ability in the art to rapidly absorb drugs with which it is presented (e.g. *Remington*, pg. 710). The tablet formulation of Ohno is merely responsible for

facilitating rapid presentation of the drug. Turning to the state of the art, there are other buccal formulations known in the art which release active ingredients but are not necessarily rapidly dissolved or disintegrated. A well known example of this is cough drops, such as those produced by Halls'. The website (http://www.gethalls.com/products.aspx) clearly advertises products which are differentiated on the basis of release. That is to say, where the products employ faster release of the active, it is advertised in order to differentiate over the traditional buccal cough drop formulations.

As such, the Examiner interprets that which is known in the prior art regarding rapid release of a drug from a given formulation to be based on the formulation itself rather than the area to which it is administered. Stated another way, simply claiming that it is a buccal administration form does not appear to distinguish over the chemical makeup which said form comprises. That being said, Applicants' amended limitation of "a buccal formulation comprising", as well as the previously considered claim 4, is broadly and reasonably interpreted as reciting little more than a location to which the composition is administered.

Lastly, Applicants' remarks directed to the methods of manufacturing the composition of Ameraal are unpersuasive, namely since the instant claims are directed to a composition rather than its method of production. More importantly, Applicants are again arguing limitations which do not appear in the claims currently under consideration. There are no method limitations which appear within the instant composition claims (e.g. product-by-process limitations; MPEP §2113).

For these reasons, Applicants' arguments are found unpersuasive. Said rejection is therefore **maintained**.

Claims 1 and 8-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kono et al. (USPN 4,748,032) [*emphasis added to reflect cancelled claims*].

The limitations of the amended claim 1 and claim 36 are discussed above. Concerning the limitation of "active agent", the Examiner interprets said phrase in light of Applicants' definition provided in the instant disclosure (see pg. 13, lines 1-6) as broadly and as reasonably as any agent (see MPEP §2111), such as one which has a flavor or nutritional value to it. Claims 8-10 recite the composition of claim 1 as further comprising at least one carbohydrate in the form of alginate, pectin or either of their derivatives. Claims 11 and 12 recite weight percent limitations of alginate within the composition.

The invention of Kono is directed to a method for preserving edible (e.g. food) compounds by encapsulating said compounds in a formulation comprising oligosaccharide-based components (Abstract). A solution form of the oligosaccharide is taught as being prepared from which a dry, powder form is achieved by using such well-known techniques as freeze-drying (col. 3, lines 41-45). Kono further teaches that said oligosaccharides are added depending on the kind and properties of the food of interest and usually ranges from 3 to 50 wt% based on the weight of the food (col. 3, lines 54-58). The oligosaccharides which are used by Kono are taught as being effective preservatives when used alone and even more effective when used in combination; such pairings including β-limit dextrin and sodium alginate (col. 3, lines 59-67).

The reference does not expressly teach the compositional ranges of alginate or alginate derivatives, as claimed by Applicants. Since the values and formats of each parameter with

respect to the claimed composition are adjustable, it follows that each is a result-effective parameter that a person having ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. In the instant case, Kono expressly teaches that 1.) the oligosaccharide(s) are more effective when employed in concert, 2.) the oligosaccharide(s) may comprise as high as 50 wt% of the composition per weight of the food preserved, and 3.) the amount will vary depending on the kind and properties of the food being preserved. Thus, it would have been customary for an artisan of ordinary skill, to adjust the amount of sodium alginate coupled with β-limit dextrin in the composition, in order to achieve the desired degree of preservation. Thus, absent some demonstration of unexpected results from the claimed parameters, optimization of any of these parameters would have been obvious at the time of Applicants' invention.

RESPONSE TO ARGUMENTS

Applicants' arguments with regard to the rejection of claims 1 and 8-12 under 35 USC 103(a) as being unpatentable over the teachings of Kono et al. have been fully considered but they are not persuasive.

Applicants allege that the amended claim 1, is free of the rejection over Kono et al. and that claims 8-12 which depend from the amended base claim likewise are allowable since the limitation of claim 4 which was not rejected by Kono et al. previously, now appears in the amended base claim.

This argument is interpreted by the Examiner as being similar to that which was set forth above with respect to the Ameraal reference. Since the reference makes no mention of a buccal-melt formulation, the reference is considered as teaching away.

In response, the Examiner respectfully disagrees maintains the rejection for the reasons already made of record with regard to the Ameraal reference. Of particular note is the manner in which the limitation is amended into the claim, namely that the formulation is a buccal-melt product comprising the previously rejected formulation of claim 1. As discussed above, the amended limitation is broadly and reasonably considered as conveying to the ordinarily skilled artisan a location within which to place the formulation of claim 1. Further considering the Applicants' instant disclosure and the state of the art, it is discerned that properties such as rapid active release which may be garnered such buccal formulations (i.e., allegedly, the most critical feature) is at the behest of the actual composition of the formulation rather than the mere claim that it is administered to buccal tissue. Since a buccal administration form comprising the composition has been previously rejected, it is respectfully maintained that Applicants have not sufficiently distinguished the instant composition from those which are known in the art.

For these reasons, Applicants' arguments are found unpersuasive. Said rejection is therefore **maintained**.

All claims under consideration remain rejected; no claims are allowed. As such, Applicants' Request for Rejoinder pursuant to MPEP §801.04, while having been fully considered, is respectfully denied at this time.

CONCLUSION

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

CORRESPONDENCE

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey T. Palenik whose telephone number is (571) 270-1966. The examiner can normally be reached on 7:30 am - 5:00 pm; M-F (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on (571) 272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jeffrey T. Palenik/
Examiner, Art Unit 1615

/Robert A. Wax/
Supervisory Patent Examiner
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